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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,972	02/14/2002	Richard J. Whitley	UAB-16102/22	5479
25006	7590	03/08/2004	EXAMINER	
GIFFORD, KRASS, GROH, SPRINKLE ANDERSON & CITKOWSKI, PC 280 N OLD WOODARD AVE SUITE 400 BIRMINGHAM, MI 48009			PRIEBE, SCOTT DAVID	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM  
**Advisory Action**

Application No.

10/009,972

Applicant(s)

WHITLEY ET AL.

Examiner

Scott D. Priebe

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 February 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.  
2. ☒ The proposed amendment(s) will not be entered because:  
(a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☒ they raise the issue of new matter (see Note below);  
(c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
4. ☒ Newly proposed or amended claim(s) 17, 18 and 20-22 would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.  
6. ☒ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.  
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:


Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: \_\_\_\_\_.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.  
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.  
10. ☒ Other: See Continuation Sheet



Scott D. Priebe  
Primary Examiner  
Art Unit: 1632

Continuation of 2. NOTE: The proposed amendment to the specification raises the issue of new matter. The Rule 66 amendment filed with the application did not contain this amendment. Furthermore, this amendment was filed with the International Bureau during the examination phase, and is not part of the original disclosure of either the PCT application or of the instant National Stage application. Proposed new claim 26 includes a previously unclaimed limitation, which would require further search and consideration.

Continuation of 5. does NOT place the application in condition for allowance because: With respect to the rejection under 35 USC 112, 1st para., see comments under item 2. With respect to the rejections under 35 USC 102 & 103, arguments relying upon the proposed claims are moot, since the proposed amendments have not been entered. With respect to the rejection over Wechsler and Toda, Applicant paraphrases para. 23 of Wechsler and then asserts that to modify the teachings of Wechsler would be contrary to its teachings. This asseertion has not been explained, and is unreasonable since Toda is relied upon to show that one of skill in the art knew how to incorporate an IL-12 expression cassette into a vector, which Wechsler (para. 25) taught to do. Also, para.23 of Wechsler teaches that the vector should not spotaneously reactivate, not that it be capable of spontaneous reactivation, as asserted by Applicant. With respect to the rejection over Adreansky and Toda, Adreansky generally teaches that genes encoding other proteins that alter the immune reponse toward tumor cells could be used in place of the IL-4 gene, and Toda shows that IL-12 is such a protein and that one can express IL-12 dimers from a vector in the context of treating cancer. It is unclear what parameters Applicant is referring to, or how varying them would require anything more than routine optimization.

Continuation of 10. Other: With respect to the "revised" declaration under R. 131, it is noted that the declaration is incomplete, as it fails to either include or unambiguously identify the evidence referred to in para. 7. .